

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.

Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this part:

Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable to Reconsideration of Disallowances [Note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification];

Part 74—Administration of Grants;

Part 75—Informal Grant Appeals Procedures;

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services, Effectuation of title VI of the Civil Rights Act of 1964;

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80;

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance;

Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance.

PART 1008—ADVISORY OPINIONS BY THE OIG

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AUTHORITY: 42 U.S.C. 1320a-7d(b).

SOURCE: 62 FR 7357, Feb. 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a-7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity, or by counsel

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on behalf of the requesting individual or entity, provided all other requirements of this part are satisfied (including the requirement that the requesting individual or entity provide the certifications required in accordance with §1008.38 of this part).

(b) An individual or entity may request an advisory opinion from the OIG regarding any of five specific subject matters described in §1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ or any other agency of the Government.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in §1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

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(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

(b) *Exceptions.* The OIG will not address through the advisory opinion process—

(1) What the fair market value will be, or whether fair market value was paid or received, for any goods, services or property; or

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in §1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) Advisory opinion request will not be accepted, and/or opinions will not be issued when—

(1) The request is not related to a named individual or entity;

(2) The same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in § 1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests that the requestor address may be obtained from the OIG. Requests should be made in writing, specify the subject matter, and be sent to the headquarter offices of the OIG.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may effect the content of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) *Responsibility for fees.* The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) *Payment Method.* Payment for a request for an advisory opinion must be made to the Treasury of the United States, as directed by OIG.

(c) *Calculation of costs:* Prior to the issuance of the advisory opinion, the

OIG will calculate the costs incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such person. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waivable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section.

(3) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section.

(4) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor

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makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(5) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point.

(6) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 1008.33.

(2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on non-legal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as quality improvement organizations, to

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obtain medical opinions on specific issues.

(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in § 1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

Subpart D—Submission of a Formal Request for an Advisory Opinion

§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§ 1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1128A or 1128B of the Act or the specific provision of § 1001.952 of this chapter about which an advisory opinion is sought:

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,¹ including—

- (i) Background information,
- (ii) For existing arrangements, complete copies of all operative documents,
- (iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,
- (iv) Detailed statements of all collateral or oral understandings, if any, and
- (v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in §1008.37 of this part;

(6) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from CMS about the arrangement that is the subject of the advisory opinion request; and

(7) Each requesting party's Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990-0213)

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social

Security Act (42 U.S.C. 1320a-3(a)(1)) and part 420 of this chapter.

(Approved by the Office of Management and Budget under control number 0990-0213)

[67 FR 11936, Mar. 18, 2002]

§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief."

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification from all requestors: "The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake." This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase "if the OIG issues a favorable advisory opinion" should be added to the certification.

(c) The certification(s) must be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(3) The managing partner of the requestor, if the requestor is a partnership; or

(4) The managing member, or comparable person, if the requestor is a limited liability company.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by §1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any

¹The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.

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time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.38 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from CMS about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§ 1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in § 1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

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Subpart E—Obligations and Responsibilities of the OIG

§ 1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Formally decline to accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in § 1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts

could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After OIG has notified the requestor of the full amount owed and OIG has determined that the full payment of that amount has been properly paid by the requestor, OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998; 73 FR 15939, Mar. 26, 2008]

§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG's intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual

or entity may discontinue or modify, as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To *rescind* an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Recission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To *terminate* an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To *modify* an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

[63 FR 38326, July 16, 1998]

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, or any other Department or agency of the United States in connection with an

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advisory opinion request under the procedures set forth in this part generally will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in §1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in §1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

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§ 1008.55 Admissibility of evidence.

(a) The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A or 1128B of the Act.

(b) An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A or 1128B of the Act or any other law.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG's opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other Federal, State or local government agency, such advisory opinion may not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency. The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies.

(b) An advisory opinion issued under this part will not bind or obligate any agency other than the Department. It will not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]